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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Zhaoyang Li
Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,150	SOO, CHIA	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to methods comprising identifying compounds expressed by fetal tissues and applying the compounds to the skin of a mammal, classified in class 435, subclass 520.

II. Claim 3, drawn to a method comprising identifying compounds that block the expression of compounds with higher expression in adult tissues and applying the blocking compounds to the skin of a mammal, classified in class 424.

III. Claims 4-14, drawn to a cosmetic or pharmaceutical composition comprising compounds expressed by fetal tissues, classified in class 424, subclass 401.

IV. Claims 15-16, 28-38, 43-44, and 50-53, drawn to methods comprising applying to skin a composition comprising a small leucine rich proteoglycan compound (SLRPs), classified in class 514, subclass 2.

V. Claims 17-27, drawn to a cosmetic or pharmaceutical composition comprising a small leucine rich proteoglycan compound (SLRP), classified in class 530, subclass 395.

VI. Claims 28-30, 32-36, 39-43, and 45-49, drawn to methods of modulating a skin condition comprising modulating the level of a glycosaminoglycan (GAG), classified in class, 424, subclass 94.1.

Claim 28 link(s) inventions IV and VI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 28. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the different inventions involve the application of

unrelated compounds to the skin. The methods of invention I involve compounds from fetal tissue, whereas the compounds in invention II are compounds that block expression of compounds in adult tissue. As such, the inventions are not capable of use together and have different modes of operation and effects. the inventions as claimed. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus, the search for each invention is not coextensive and it would place and undue burden on the examiner to search and examine both inventions together.

2) Invention II is unrelated to any of inventions III-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, none of inventions III-VI involve the use of compounds that block expression of a compound found in adult tissue. Likewise, the methods of invention II do not utilize any of the compounds or modulation methods of invention III-VI. As such, the inventions are not capable of use together and have different modes of operation and effects. Thus, the search for each invention is not coextensive and it would place and undue burden on the examiner to search and examine invention II and any of inventions III-VI together.

3) Invention I and invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition comprising compounds expressed by fetal

tissues of invention III can be used in materially different processes of use than those of invention I, such as the use of the compounds in *in vitro* assays.

4) Inventions I and inventions IV-VI are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, none of inventions IV-VI involve the use of compounds expressed by fetal tissue. Likewise, the methods of invention II do not utilize any of the compounds or modulation methods of invention IV-VI. As such, the inventions are not capable of use together and have different modes of operation and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants Thus, the search for each invention is not coextensive and it would place and undue burden on the examiner to search and examine invention I and any of inventions IV-VI together.

5) Invention III and inventions IV-VI are directed to an unrelated product and process and unrelated products. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of inventions IV and VI utilize the application of compounds such as SLRPs or enzymes capable of modulating GAGs which are unrelated to a composition of compounds expressed in fetal tissue. Thus, the composition of invention III cannot be used in the methods of inventions IV or VI. Further, the composition of invention V is unrelated to the composition of invention III as each composition has materially different chemical, structural,

and biological properties and is made using different techniques and reagents. Thus, the search for each invention is not coextensive and it would place and undue burden on the examiner to search and examine invention III and any of inventions IV-VI together.

6) Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compositions comprising SLRPs can be used in materially different methods, such as the use of the SLRPS in in vitro assays.

7) Inventions V and VI are directed to an unrelated product and process and unrelated products. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the SLRP cannot be used in the methods of invention VI which utilize enzymes capable of modulating a GAG.

8) Inventions IV and VI are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each method utilizes compounds with materially different structural, chemical, and biological properties for the modulation of materially different target compounds. As such, the inventions are not capable of use together and have different modes of operation and effects. Furthermore, the inventions as claimed do not

encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus, the search for each invention is not coextensive and it would place and undue burden on the examiner to search and examine both inventions together.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, different search requirements, and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

1) for inventions I and III-species of compounds expressed by fetal tissues

a) cell lysates or extracts

b) media

c) partially purified or individually purified compounds

d) genetically modified compounds.

The species are independent or distinct because each species is made using materially different techniques and has materially different chemical properties such that the search for each species is not coextensive with the others. Thus, it would place an undue burden on the examiner to search and examine all species together.

2) for inventions IV and V- species of SLRPs

a) fibromodulin

b) lumican

c) decorin

d) biglycan

The species are independent or distinct because each species is materially different chemical, structural, and biological properties such that the search for each species is not coextensive with the others. Thus, it would place an undue burden on the examiner to search and examine all species together.

3) for invention VI- species of GAGs

a) dermatan sulfate

b) chondroitin sulfate

c) keratan sulfate

The species are independent or distinct because each species is materially different chemical, structural, and biological properties such that the search for each species is not coextensive with the others. Thus, it would place an undue burden on the examiner to search and examine all species together.

4) for invention VI-species of enzymes that modulate a GAG

a) chondroitinase AC

b) chondroitinase B

c) endo-beta-galactosidase

d) keratanase

e) keratanase II

f) Bc keratanase II

The species are independent or distinct because each species is materially different chemical, structural, and biological properties such that the search for each species is not coextensive with the others. Thus, it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for

electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER